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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/342,993 06/29/99 POIRIER J 08523/005002

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HM12/1031

EXAMINER

CARLSON, K

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/342,993

Applicant(s)

POIRIER, JUDES

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/727,693.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

This Office Action is in response to the after-final amendment filed October 19, 2001 (Paper #7). This after-final amendment has been entered.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims 6 and 7 have been canceled. Claims 1-5 and 8 are currently pending and are under examination.

Withdrawal of Rejections:

The rejection of Claim 6 under 35 USC 112, first paragraph, is withdrawn.

The rejection of Claims 1-8 under 35 USC 102(b) is withdrawn.

The rejection of Claims 1-8 under 35 USC 103 is withdrawn.

Maintenance of and New Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method which comprises "determining the number of copies of apoE4 gene alleles in said subject" and the claims do not set forth the steps that would be taken to determine the number of apoE4 alleles in the subject. Specifically, at page 1 of the specification, it is apoE which comprises three common alleles: apoE2, apoE3, and apoE4. Therefore, it is not clear if the determination is of the apoE4 gene copy number, or determining apoE, apoE2 and/or apoE3 gene presence and/or copy number because these genes would be considered to be alleles of the apoE4 gene. If the latter

is true, then the presence or copy number of the apoE4 gene would not be determined because it is the apoE4 alleles that are to be determined. Additionally, the term "respond" in the phrase "respond to a cholinomimetic drug" is unclear because it is not clear what the response is, that is, is the response improved cognition or does it involve phospholipid transport? Further, it is not clear why one would determine the number of alleles or the apoE4 gene copy number if it is the absence of apoE4 gene allele that indicates a predisposition to respond to a cholinomimetic drug. Alternatively, if it is the apoE4 alleles that are determined, how/when is the apoE4 gene presence determined?

Claims 4 (b) and 5(b) recite a method which comprises "determining the number of copies of apoE4 gene alleles in said subject" and the claims do not set forth the steps that would be taken to determine the number of apoE4 alleles in the subject.

Specifically, at page 1 of the specification, it is apoE which comprises three common alleles: apoE2, apoE3, and apoE4. Therefore, it is not clear if the determination is of the apoE4 gene copy number, or determining apoE, apoE2 and/or apoE3 gene presence and/or copy number because these genes would be considered to be alleles of the apoE4 gene. If the latter is true, then the presence or copy number of the apoE4 gene would not be determined because it is the apoE4 alleles that are to be determined. Additionally, it is not clear why one would determine the number of alleles or the apoE4 gene copy number if it is the absence of apoE4 gene allele that places a patient into a subgroup. Further, in Claim 4(b), it is not clear what "subgroup" the patient would be placed in. Alternatively, if it is the apoE4 alleles that are determined, how/when is the apoE4 gene presence determined?

Applicants urge that PCR can be used to determine the number of apoE4 alleles and refers to the specification pages 7-8. This method identifies the presence of the gene, but not the copy number.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,935,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of patent claim 1 is the same as the method of application Claim 1 except that subject of patent Claim 1 has cognitive impairments and the method of application Claim 1 has Alzheimer's, which is encompassed in the phrase "cognitive impairments". The method of application Claims 4 and 5 are encompassed in patent Claims 1-4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

October 29, 2001



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER